

REMARKS / ARGUMENTS

Claims 13-16, 18 and 31-39 are pending. Claims 12, 17, 19-21 are cancelled. The dependency of the remaining claims is revised accordingly. Minor grammatical errors are corrected in claims 31 and 35. This amendment does not affect the scope of the claims. New claims 38 and 39 are supported by the examples and throughout the specification. No new matter is added by this amendment.

Claims Rejections - 35 USC §103

The Examiner has rejected claims 12-21 and claims 31-37 under 35 USC §103(a) as unpatentable over Skotnicki et al, US Patent No. 5,362,718 ("*Skotnicki*") in view of US Patent No. 5,516,770 ("*Waranis*") and GB 237611 ("*Haeberlin*").

Applicants respectfully traverse this rejection.

There is no teaching in the art of any problems associated with CCI-779 parenteral formulations much less the specific problems recognized by the invention. In the absence of recognition of the problem in the art, there can be no motivation in the art to look for a solution.

Skotnicki describes hydroxyesters derivatives of rapamycin, including CCI-779. However, there is no teaching in *Skotnicki* which would lead one to select CCI-779 from amongst the other hydroxyesters of rapamycin. *Waranis* and *Haeberlin* do not teach or suggest formulations containing CCI-779 having the components of the present formulations. As admitted by the examiner, there is no teaching in *Waranis* of an antioxidant. *Haeberlin* is relied upon for teaching the use of carboxylic acids to stabilize macrolides generally teaching a 0.05% to 5% acid concentration range. However, *Haeberlin* does not describe the use of α -tocopherol as an antioxidant. Further, experimental evidence generated by assignee has shown that use of α -tocopherol in excess of 1.5% can lead to increased oxidative instability, a finding which is counter to what would have been expected based on what is known in the

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cited art about anti-oxidants. This data is illustrated in Example 3 of US Patent Publication No. US-2007-0142422-A1, published June 21, 2007.

Thus, the cited combination of documents do not provide the suggestion required for the present invention and in fact, would lead one of skill in the art to a composition which would not achieve the benefits of the present invention.

Reconsider and withdrawal of the rejection is requested.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper, or credit any overpayment in any fees, to Deposit Account Number 08-3040.

Respectfully submitted,
HOWSON & HOWSON LLP
Attorneys for Applicants

By 
Cathy A. Kodroff

Registration No. 33,980
501 Office Center Drive, Suite 210
Fort Washington, PA 19034
Ph: (215) 540-9210
Fax: (215) 540-5818